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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,539	06/19/2006	Andreas Lendlein	26538-0014	6451

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EXAMINER	
HORNBERGER, JENNIFER LEA	
ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
06/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/560,539	LENDLEIN ET AL.	
	Examiner	Art Unit	
	JENNIFER L. HORNBERGER	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Langer et al. (US 6,160,084).

Regarding claim 1, Langer et al. disclose a stent (col. 12, ln. 15) comprising a biodegradable SMP material for use in a non-vascular or vascular field, wherein the SMP material is selected from the group consisting of covalent polymer networks and covalent polymer interpenetrating networks (col. 9, ln. 39-52).

Regarding claim 5, Langer et al. disclose the SMP is selected from among the following: polymer networks, thermoplastic SMP materials, composite materials, and blends (col. 9, ln. 5-52).

3. Claims 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Igaki (EP 1033145 A1).

Regarding claim 11, Igaki discloses a method of manufacturing biocompatible SMP materials comprising the processing of SMP material to a stent by one of the following extrusion methods, coating methods, metal casting methods, and spinning and weaving methods (paragraph 33).

Regarding claim 12, Igaki discloses a system, comprising a stent (1) of a biodegradable SMP material (paragraph 36), and including at least one of the following: a temperature controlled balloon catheter and a balloon catheter with an optical fiber (paragraphs 51-52).

Regarding claims 13 and 14, Igaki discloses a method for minimal invasive implantation of a stent, comprising the following steps: placing a stent of a biodegradable SMP material onto a temperature controlled balloon or a balloon catheter with an optical fiber, wherein the SMP material has two shapes in the memory and wherein this material was programmed to two shapes, wherein the first shape, compared to a second shape, is a tubular shape with a larger diameter, inserting the stent to the desired position, wherein the SMP material exists in its second shape; heating the stent by inserting a heating medium into the catheter; activating the SMP effect to bring the stent into the first shape, and removing the balloon catheter (paragraphs 51-52).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Igaki (EP 1033145 A1) in view of Langer et al. (US 6,160,084).

Regarding claim 1, Igaki discloses a stent (1) comprising a biodegradable SMP material for use in a nonvascular or vascular field (paragraphs 32 and 36). Igaki fails disclose the SMP material is selected from the group consisting of covalent polymer networks and covalent polymer interpenetrating networks. Langer et al. disclose a stent (col. 12, ln. 15) comprising a

biodegradable SMP material for use in a non-vascular or vascular field, wherein the SMP material comprises thermoplastic polymers, covalent polymer networks, or covalent polymer interpenetrating networks (col. 9, ln. 5-52). It would have been obvious to one of ordinary skill in the art to substitute the thermoplastic SMP material of Igaki with a SMP material comprising covalent polymer networks or covalent polymer interpenetrating networks since Langer et al. disclose thermoplastic material, covalent polymer networks, and covalent polymer interpenetrating networks and the advantages of each are known in the art for forming SMP material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to select a SMP material comprising covalent polymer networks or covalent polymer interpenetrating networks, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Regarding claims 2 and 3, Igaki discloses the stent comprises one of the following: a basic structure of a biodegradable plastic material and a degradable metal coated by SMP material, wherein the degradable metal includes one of the following: a magnesium alloy, pure magnesium, and a composite of magnesium or a magnesium alloy with biodegradable polymer (paragraph 32).

Regarding claim 4, Igaki discloses the stent comprises additional additives selected among x-ray contrast materials and medically effective compounds (paragraph 68).

Regarding claim 5, Igaki in view of Langer et al. disclose the SMP material is selected from among the following: polymer networks, thermoplastic SMP materials, composite materials and blends (paragraphs 32 and 36).

Regarding claim 6, Igaki in view of Langer et al. disclose the SMP material is selected from among at least one of the SMP materials in which the SMP effect is induced thermally, is

photo-induced, wherein the SMP is biocompatible, haemocompatible, and wherein the SMP reveals a particle free degredation behavior (paragraphs 51-52).

Regarding claim 7, Igaki discloses the network includes at least one of the following: caprolacton units and pentadecalacton units (paragraph 32).

Regarding claim 8, Igaki discloses the network consists of cross-linked caprolactonmacromonomers (paragraphs 32 and 36).

Regarding claims 9 and 10, Igaki discloses the stent comprises a surface coating that modifies haemocompatibility (paragraph 71).

Response to Arguments

6. Applicant's arguments filed 04/07/2009 with respect to claims 11-14 have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "the SMP material selected from the group consisting of covalent polymer networks and covalent polymer interpenetrating networks") are not recited in the rejected claims 11-14. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

7. Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
06/08/2009

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734